



UNITED STATES PATENT AND TRADEMARK OFFICE
TRADEMARK EXAMINING OPERATION

In re Application of:

PETER T. PUGLIESE

Serial No.: 09/989,019

Filed: November 21, 2001

Title: THE USE OF COMBINED FLAVONES
AND ISOFLAVONES TO TREAT
CELLULITE.

Art Unit No.: 1617

Primary Examiner: San-ming Hui

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**DECLARATION OF P. T. PUGLIESE UNDER 37 C.F.R. § 1.68 AND 1.132,
AND MPEP 2107.01 AND 2107.03**

1. I, Peter T. Pugliese, M.D., declare that the following statements are made of the Declarant's own knowledge and are true, and that all statements made on information and belief are believed to be true; and that the Declarant is warned willful false statements, and the like, are punishable by fine or imprisonment, or both (18 US Code §1001) and may jeopardize the validity of the above-captioned application or on any patent issuing thereon;

2. Declarant is President of The Pugliese Group, Inc., 4408-B Pottsville Pike, Reading, PA 19605, conducting biomedical research in skin physiology in Reading, PA, and is the sole applicant for letters patent on the captioned case.

3. Declarant is author of a clinical study for the treatment of the cosmetic condition in women called cellulite, which study involves applying candidate formulations seeking to alleviate cellulite, as may be evaluated by clinical examination of test subjects.

4. The underlying patent specification sets forth a protocol (page 12 et al) for testing of candidate products for efficacy, which protocol entails ultrasound measurements on thigh diameters, and which measurements were employed in evaluating an exemplary isoflavone, genistein, disclosed inter alia, in the Specification as being an active component of each of the recited Formulas # 1, # 2, and # 3;

5. Genistein was first evaluated for its potential effects on the fat reduction of female thighs, as to be determined by ultrasound measurements, which measurements are presented graphically in the tricolor bar charts depicted in Exhibit A, titled "Density Measurements of Ultrasound Scans";

6. Such measurements were made at 1 (blue bar), 28 (purple bar), and 56 (yellow bar)

day intervals starting from initial topical application of Formula No. 3, to assess average epidermis density, average papillary dermis density, and average reticular dermis density, respectively;

7. Papillary dermis density is an indicator of connective tissue cell replacement, while reticular dermis density is an indicator of reduction in fat cell size and/or number;

8. As a medically licensed physician and clinician, it is my professional opinion that the exemplary isoflavone, genistein, shows a measurable increase (c. 5 units) in epidermis density at 28 days, followed by a slight dip at day 56; a progressive increase in papillary dermis density from c. 27 units at day one to c. 48 units at day 56; and, a progressive increase in reticular dermis density from c. 35 units at day 1 to c. 66 units at day 56;

9. Five women with clinically determined moderate cellulite were treated with an emulsion like Formula #3, but having active components, save genistein being omitted, and the emulsifiers and emollients being retained, with twice daily applications to both thighs; the degree of cellulite was determined by measuring visual ratio of connective tissue to fat infiltration into connective tissue;

10. Based on ultrasound measurements, made at both four and eight weeks, the amount of fatty tissue decreased, while the amount of connective tissue increased by about 8% at four weeks, and by 19% at eight weeks, respectively (Exs. B & C).

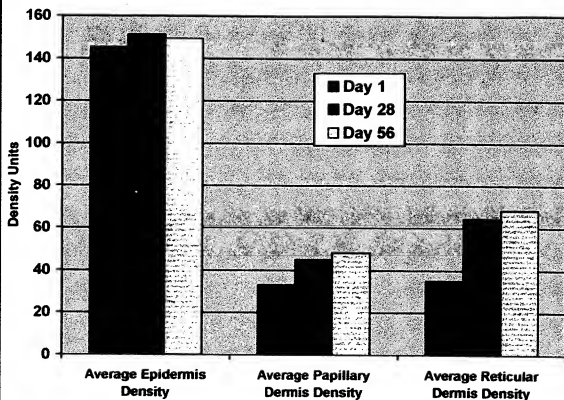
11. From the foregoing graphic presentations of my clinical observations, I am able to conclude that genistein, in combination with afore-described active components, or even if used alone in an emulsion, is capable of inhibiting the undesirable destructive effects of estrogen on connective tissue, like collagen, and it thus provides a positive effect on treating cellulite, as indicated by measuring their visual ratios as recited above.

12 Further Declarant sayeth not.

Date: April 30, 2001
Exhibits A, B, and C

Peter T. Pugliese, M.D.
Peter T. Pugliese, M.D.

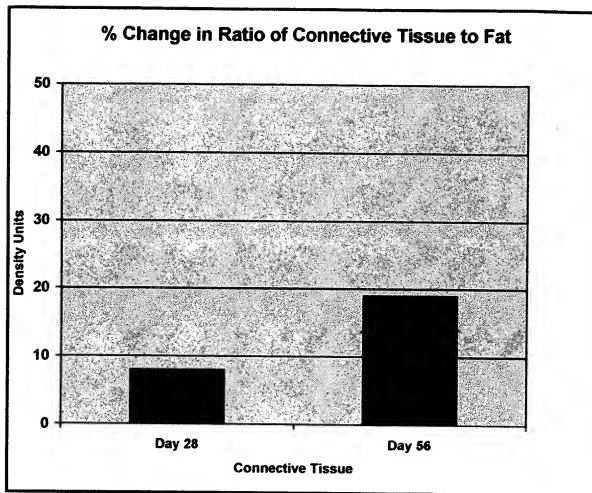
Density Measurements of Ultrasound Scans



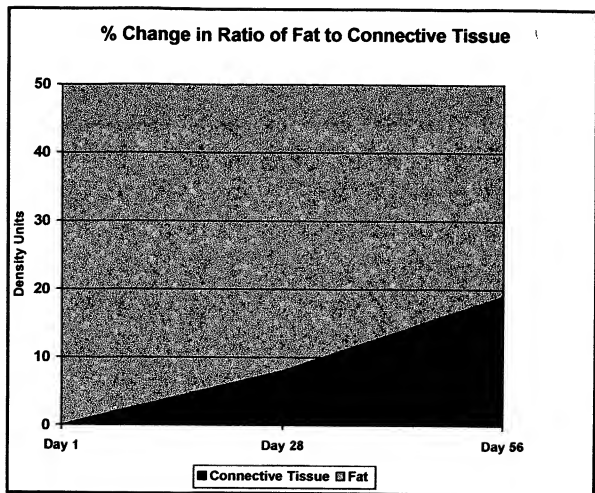
EFFECTS OF GENISTEIN ON FAT REDUCTION OF THIGHS AS DETERMINED BY ULTRASOUND.

An increase in density indicates a reduction in fatty tissue.

EX. A TO R, 132 DECLR. OF INVENTOR IN USSN 09/989,019



EX. B TO R. 132 DECLR. OF INVENTOR IN USSN 09/989,019



EX. C TO R. 132 DECER.OF INVENTOR IN USSM 09/989,019